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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,366

03/18/2004

Frederic Triebel

1057-04

7996

35811 7590 05/13/2010  
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EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

NOTIFICATION DATE

DELIVERY MODE

05/13/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pto.phil@dlapiper.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/803,366	<b>Applicant(s)</b> TRIEBEL, FREDERIC	
	<b>Examiner</b> David A. Saunders	<b>Art Unit</b> 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 31-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/16/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **TRANSFER OF APPLICATION**

This application has been transferred to a different examiner. See information provided under **CONTACTS**.

### **AMENDMENT ENTRY**

The amendment of 12/29/08 has been entered. Claims 31-38 are pending and are under consideration.

### **OBJECTIONS/REJECTIONS OF RECORD WITHDRAWN**

The amendment has overcome the following grounds of objection or rejection:

The objection to claim(s) 37-38.

The rejections of claim(s) 31-32 under 35 USC 112, 2<sup>nd</sup> para.

Upon reconsideration the following grounds of rejection are newly stated.

### **REJECTION(S) UNDER 35 U.S.C. 112, FIRST PARAGRAPH**

Claims 31-38 are rejected under 35 U.S.C. first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant was not in possession of the peptide fragment of SEQ ID NO:1 or the fragment of SEQ ID NO: 2, which "peptide binds the EP motif". Also, applicant has failed to describe any "peptide that shares at least 50% identity with a fragment" of either of these amino acid sequences.

More specifically, the Office finds that applicant did not directly possess, identify, or exemplify any “fragment” of SEQ ID NO:1 or of SEQ ID NO:2 with the claimed binding property. To the contrary, what applicant possessed, identified, and exemplified were deletion mutants of SEQ ID NO:1 which did not bind to the Lag-3 protein having the EP motif (See Fig. 2A and see paras. [0071]+ of US 2004/0171551, cited on PTO-892). However, it is one thing to have possession of a protein that has a “fragment” deleted therefrom (which applicant possessed) and to show that the deletion variant/mutant lacks a function, but it is another thing to have possession of the deleted fragment, per se (which applicant did not possess), and to show that the fragment actually has the function. Possession of a deletion variant/mutant that lacks a function does not prove that the deleted fragment actually has the function. This is because one has no idea whether the claimed property of binding to an “EP motif” is a property that can be embodied by a linear subsequence of contiguous amino acid residues (i.e. a “fragment”) or is a property that can only be embodied conformationally, by non-contiguous residues. Since one has no idea whether there is, in fact, any linear subsequence of SEQ ID NO:1 [of claim 31] which has this binding property (it has not even been demonstrated that an isolated polypeptide of SEQ ID NO:2, per se, has this binding property), the only embodiment of instant claim 31 that has been described is that of the full length LAP polypeptide of SEQ ID NO:1.

Even if applicant traverses the above position, that he was only in possession of the full length LAP polypeptide of SEQ ID NO:1, then the Office shall maintain that smallest “fragment” of SEQ ID NO:1 [of claim 31] which has the property of binding an EP motif, that applicant described at the time of filing, was the polypeptide of SEQ ID NO:2, per se [of claim 32]. This is because applicant’s examples have demonstrated nothing, with any of the deletion mutants, that would lead one to look for an “EP motif” binding fragment toward the N-terminus of LAP protein (i.e. anywhere to the left of where SEQ ID NO:2 starts, within SEQ ID NO:1).

Additionally, even if one were to grant that the full length polypeptide of SEQ ID NO:2 has the property of binding an EP motif, the Office shall further hold the position

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that applicant's disclosure has never identified any smaller peptide "fragment" of SEQ ID NO:2 which has the claimed property of binding an EP motif. Applicant has not revealed how long it is, and where it is within SEQ ID NO:2. Applicant has provided no direction in the disclosure that would lead one to consider that LAP protein is one member of a family of proteins which have the property of binding to EP motifs and that there is a common, art-recognized structure within the sequences of such a family of proteins that correlates with their property of binding to EP motifs. Thus, even any peptide "fragments" that might be "100% identical to a portion of the amino acid sequence of SEQ ID NO:1 [or SEQ ID NO:2]", as in instant claim 37 [or 38], have not been described.

In addition, with respect to claims 33-36, one only knows what the motif of the target being bound might be, rather than what the motif of the claimed peptide that actually does the binding might be. The Office doesn't care what the motif of the target being bound looks like; the Office wants to know what the motif of the claimed binding peptide looks like. If applicant hasn't revealed it (such as how long it is, and where it is within SEQ ID NOS:1 or 2), the claim is basically unsearchable, because the claims encompass fragments of SEQ ID NO:1 that are all over the map from residue 238 to the COOH terminus, or fragments of SEQ ID NO:2 that are all over the map from residue 1 to the COOH terminus.

Further, since no residues within SEQ ID NOS:1 or 2 have been identified as being critical for binding the EP motif, one would have no idea of whether or not some polypeptide as long as SEQ ID NOS:1 or 2 and having 50% sequence identity thereto, would or would not be a peptide that could bind to an "EP motif". See the rationale set forth in Example 11A of The Written Description Training Materials (Revision 1, March 25, 2008, available at <http://www.uspto.gov/web/menu/written.pdf>). It follows then, that i) since polypeptides as long as SEQ ID NOS:1 or 2 and having 50% sequence identity thereto have not been described, and ii) since no subsequences/ "fragments" of contiguous residues within SEQ ID NOS:1 or 2 have been described, that applicant has failed to describe any "peptide that shares at least 50% identity with a fragment of the

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amino acid sequence of SEQ ID NO:1" [claim 31] or any "peptide that shares at least 50% identity with a fragment of the amino acid sequence of SEQ ID NO:2 [claim 32].

## **REINSTATED REJECTION(S) UNDER 35 USC 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 31-36 are rejected under 35 U.S.C. 102(a) as being anticipated by louzalen et al (Eur. J. Immunol. (2001) 31:2885-2891; cited on PTO-1449 of 3/18/04).

louzalen et al teaches a LAP protein comprising both SEQ ID NO: 1 [claim 31] and SEQ ID NO: 2 [claim 32]. Instant claims 31 and 32 are open in scope to encompass the whole LAP protein of longer length, since they each recite "said polypeptide comprising". The ability to bind to a target comprising an EP motif [claims 31 and 32] is an inherent property of the C-terminal region of the LAP protein. The prior art teaching anticipates the claimed invention of instant claims 31 and 32.

Though louzalen et al does not teach the EP motifs recited in instant claims 33-36, binding of LAP protein to these target EP motifs is taken to be an inherent property of the LAP protein, based upon applicant's own disclosure.

This reference was previously applied in the Office action of 3/13/07, in which the examiner indicated that "This ground of rejection can be overcome by the submission of a certified copy of the EPO priority application in English." The EPO priority application has been considered for support of the claims now pending, as presented on 9/29/08; the Office finds that the EPO priority application does not support the instant claims, by virtue of the fact that recitations of "a peptide that shares at least 50% identity with a fragment of the amino acid sequence of SEQ ID NO:1 [or 2]" are not present in the EPO

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document. The only recitations that support anything about "a peptide that shares at least 50% identity with a fragment" are found instantly in para. [0108] of US 2004/0171551; there is no such paragraph in the EPO document.

In essence, the rejection has been properly reinstated over a reference which merely shows SEQ ID NOS:1 and 2, because the reference knocks out these members of the Markush groups of instant claims 31 and 32. These Markush groups are too big to be supported by the EPO priority application, which has no teachings of "a peptide that shares at least 50% identity with a fragment of the amino acid sequence of SEQ ID NO:1 [or 2]". The instant fact situation follows that of *In re Ruscetta* 118 USPQ 101; see reference thereto in MPEP 201.11. For this reason, applicant's claims only have benefit of the International Filing Date of 17 Sep 2002.

### **NEW REJECTION(S) UNDER 35 USC 102/103**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Nandabalan et al (WO 99/51741, cited in IDS of 10/16/08).

Nandabalan et al (WO '741) teaches a polypeptide sequence in Fig. 2 that is at least 50% identical to residues 177-372 of instant SEQ ID NO:1. This is thus taken to be a "fragment" of SEQ ID NO:1 that anticipates claim 31. The property of binding to an EP motif is properly considered to be inherent to the polypeptide of WO '741, because this polypeptide sequence includes a sequence nearly identical to instant SEQ ID NO:2 and which extends about 60 residues to the left of the start of instant SEQ ID NO:2. Since applicant has claimed the polypeptide of instant SEQ ID NO:2 as having the property of binding to an EP motif (in claim 32), it is properly taken that the polypeptide sequence of Nandabalan et al, which includes a sequence nearly identical to instant SEQ ID NO:2 would, likewise, have the property of binding to an EP motif. Claim 31 is thus anticipated.

Instant claim 32 is open in scope to encompass a polypeptide of longer length, since it recites said polypeptide comprising"; thus claim 32, like claim 31, is also anticipated.

The binding properties recited in instant claims 33-36 are also taken to be inherent to the polypeptide of WO '741 for like reasons.

Claims 31-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Yue et al (WO 01/85942, cited On PTO-892).

Yue et al (WO '942) teaches a polypeptide of 569 amino acid residues in SEQ ID NO: 15 (starts at p 17/69 of Sequence Listing). Residues 198-569 thereof have a 100% match to residues 1-372 of instant SEQ ID NO:1. Residues 435-569 thereof have a 100% match to residues 1-135 of instant SEQ ID NO:2. Instant claims 31 and 32 are open in scope to encompass a polypeptide of longer length, since they each recite "said polypeptide comprising".

The binding properties recited in instant claims 33-36 are taken to be inherent to this polypeptide of WO '942.

The 102(e) date of WO '942 to be overcome is the International Filing Date of 03 May 2001. Any earlier filing dates of the US provisional applications, listed under the



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Priority Data, are not applicable since these were all filed prior to 29 Nov. 2000. See MPEP 706.02(f)(1).

Claims 31-36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over SHIMKETS et al (WO 00/58473, cited on PTO-1449 Filed 10/18/08).

Applicant's IDS of 10/18/08 has listed SEQ ID NO:4032 of SHIMKETS et al (WO '473). Residues 47-418 of SEQ ID NO:4032 (at pp 3216-3217) have a 100% match to residues 1-372 of instant SEQ ID NO:1. Residues 284-418 of SEQ ID NO:4032 have a 100% match to residues 1-372 of instant SEQ ID NO:2. Instant claims 31 and 32 are open in scope to encompass a polypeptide of longer length, since they each recite "said polypeptide comprising".

The binding properties recited in instant claims 33-36 are taken to be inherent to this polypeptide of WO '473.

The rejection is properly stated under 102(b), not 102(a), because applicant's claims only have benefit of the International Filing Date of 17 Sep 2002; see explanation supra regarding the effective filing date, under the rejection stated over louzalen et al. Obviousness is alternatively stated, in the event that applicant should urge that SEQ ID NO:4032 has only been hypothetically translated from SEQ ID NO:4031.

## **CONTACTS**

Any inquiry concerning this communication from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays. The examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax number where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. For

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more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 5/4/10 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644